EXHIBIT 121

Chapman, Tara

From:	Chapman, Tara
Sent:	Thursday, May 31, 2012 9:55 AM
To:	maryann.holovac@fda.hhs.gov
Cc:	lisa.basham@fda.hhs.gov
Subject:	Request to move Opana ER NDA 21-610 to the Orange Book Discontinued List

Dear Ms. Holovac,

The purpose of this correspondence is to notify the Orange Book Staff and Division that Endo has discontinued marketing of the OPANA ER (oxymorphone hydrochloride) formulation in NDA 21-610 and as such would like to move the product to the Discontinued List in the Orange Book.

While the original formulation of OPANA ER (under NDA 21-610) was deemed by FDA to be safe and effective when taken according to the prescribing information, the original formulation was subject to both intentional and inadvertent abuse and misuse. Endo believes that the new formulation of OPANA ER (under NDA 201655), which is designed to be crush resistant, offers safety advantages over the original formulation (NDA 21-610) and that the original formulation (under NDA 21-610) should be discontinued for safety reasons.

This request to move Opana ER (NDA 21-610) to the Orange Book Discontinued List applies to the following dosage strengths: 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg. The Opana ER (NDA 21-610) 7.5 mg and 15 mg dosage strengths were moved to the Discontinued List previously. The Opana ER (under NDA 201655) should remain on the approved prescription drug product list as it is the currently available formulation.

If you have any questions, please contact me.

Thank you!

Kind Regards,
Tara

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